REMARKS/ARGUMENTS

Applicants respectfully request reconsideration of this application. No claims have been canceled or amended.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over

U.S. Patent Application No. 2003/0208378 of Thangaraj et al. ("Thangaraj") in view of

U.S. Patent Application No. 2004/0006553 of De Vries et al. ("De Vries"). Applicants

respectfully traverse the rejection. Note that Applicants reserve the right to swear behind

Thangaraj and/or De Vries.

Specifically, claim 1 includes the limitation, or a limitation similar thereto, of:

> enabling an administrator to define a plurality of clinical trial parameters
> through filling out fields in a set of computer forms;
> storing the clinical trial parameters in a central database;
> enabling clinical trial site personnel to enter subject enrollment data
> corresponding to at least one clinical trial defined by the clinical trial parameters
> via an Internet web portal;
> storing the subject enrollment data in the central database substantially as
> it is entered in time; and
> generating a chart displaying selected data aggregated from the subject
> enrollment data to graphically portray subject enrollment attributes pertaining to a
> selected clinical trial from among said at least one clinical trial.
> (Applicants' independent claim 1).

In contrast, Thangaraj fails to disclose **generating a chart displaying selected**

data aggregated from the subject enrollment data to graphically portray subject

enrollment attributes pertaining to a selected clinical trial from among said at least

one clinical trial as set forth in claim 1. Thangaraj merely discloses that charts may be stored in the system (Thangaraj, p. 7, para. [0100]). Thangaraj fails to disclose generating a chart as set forth in claim 1. Furthermore, Thangaraj fails to provide any specific details about the charts. Furthermore, the secondary reference, De Vries, also fails to disclose such a limitation. Therefore, claim 1 is not obvious over Thangaraj in view of De Vries because a combination of Thangaraj and De Vries does not disclose at least the above limitation set forth in claim 1. Withdrawal of the rejection is respectfully requested.

Moreover, Thangaraj fails to disclose enabling an administrator to define a plurality of **clinical trial parameters** through filling out fields in a set of computer forms. According to Thangaraj, the system in Thangaraj merely provides administration functions that allow the users to use the clinical trial setup information to collaborate with each other and administer the clinical trial (Thangaraj, p. 1, para. [0006]). The clinical trial management system in Thangaraj enables each user "to enter, retrieve, and manage data" (Thangaraj, p. 2, para. [0016]). The "data" disclosed in Thangaraj is too general as compared to the plurality of clinical trial parameters set forth in claim 1. Thangaraj does not disclose or suggest enabling an administrator to define a plurality of clinical trial parameters through filling out fields in a set of computer forms. Furthermore, the secondary reference, De Vries, also fails to disclose such a limitation. Therefore, claim 1 is not obvious over Thangaraj in view of De Vries because a combination of Thangaraj and De Vries does not disclose at least the above limitation set forth in claim 1. Withdrawal of the rejection is respectfully requested.

Furthermore, Thangaraj fails to disclose storing the **clinical trial parameters** in a central database. The Examiner analogized the user membership database (reference numeral 100 in Figure 4 of Thangaraj) to the central database set forth in claim 1. Applicants respectfully disagree because the database 100 in Thangaraj merely stores personalization and membership information (Thangaraj, p. 6, para. [0080]). Thangaraj does not disclose, suggest, or imply that the database 100 stores the clinical trial parameters. Furthermore, the secondary reference, De Vries, also fails to disclose such a limitation. Therefore, claim 1 is not obvious over Thangaraj in view of De Vries because a combination of Thangaraj and De Vries does not disclose at least the above limitation set forth in claim 1. Withdrawal of the rejection is respectfully requested.

For at least the many deficiencies in Thangaraj and De Vries, claim 1 is not obvious in view of Thangaraj and De Vries. Applicants respectfully request withdrawal of the rejection.

For at least the reasons discussed above with respect to claim 1, claim 15 is patentable over Thangaraj in view of De Vries. Withdrawal of the rejection is respectfully requested.

Claims 2-14 and 16-24 depend, directly or indirectly, from claims 1 and 15. Therefore, claims 2-14 and 16-24 are patentable over Thangaraj in view of De Vries for at least the reasons discussed above with respect to claim 1. Applicants respectfully request withdrawal of the rejection.

Furthermore, regarding claim 7, it sets forth a **subject status analysis chart** that

portrays a plurality of subject status totals pertaining to the selected clinical trial and

corresponding to a selected aggregation level. In contrast, neither Thangaraj nor De Vries

discloses such a status analysis chart. The Examiner cited para. [0083] on p. 5 of De

Vries to argue that such a limitation is disclosed in De Vries. However, according to De

Vries:

> The trial administrators desiring to create or design clinical trials may do so by
> establishing a data path from the computing device 15 (FIG. 1) to the computing
> device 12, via the network 20 to access the clinical trial management program of
> the present invention. This can be accomplished by using an Internet-based
> browser program, e.g., Microsoft EXPLORER.TM. or Netscape
> NAVIGATOR.TM.. After connecting to the computing device 12 (FIG. 1), and
> entering the username/password combination 100, on the login screen 102 of the
> inventive system as shown in FIG. 4a, the trial administrator may create a new
> trial and begin defining the various elements of the trial. Furthermore, although
> after the start of the trial modifications may not be accepted, to create new trials
> the trial administrator may modify and delete any existing trials.
> (De Vries, p. 5, para. [0083]).

The above passage cited by the Examiner from De Vries merely discloses that the

trial administrator may create a new trial and begin defining the various elements of the

trial and the trial administrator may modify and delete any existing trials to create new

trials. De Vries does not disclose or suggest a **subject status analysis chart** that portrays

a plurality of subject status totals pertaining to the selected clinical trial and

corresponding to a selected aggregation level. Likewise, Thangaraj does not disclose or

suggest the subject status analysis chart set forth in claim 7. Therefore, claim 7 is

patentable over Thangaraj in view of De Vries for at least this additional reason.

Withdrawal of the rejection is respectfully requested.

For at least the reason discussed above with respect to claim 7, claim 21 is patentable over Thangaraj in view of De Vries. Withdrawal of the rejection is respectfully requested.

Claims 8 and 22 depend from claims 7 and 21, respectively, and thus, are patentable over Thangaraj in view of De Vries. Withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit the present application is in condition for

allowance. If the Examiner believes a telephone conference would expedite or assist in

the allowance of the present application, the Examiner is invited to call C. Teresa Wong

at (408) 720-8300, x377.

If there are any additional charges, please charge Deposit Account No. 02-2666

for any fee deficiency that may be due.

Respectfully submitted,

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